

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1093630	(X3) Date Survey Completed 02/22/2023
Name of Provider or Supplier Bryn Mawr Med Spec Asso Dpt Of Gastro	Street Address, City, State 825 Old Lancaster Road, Suite 340, Bryn Mawr, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of quality assurance (QA) documentation and an interview with the laboratory director (LD), the laboratory director failed to ensure a QA program was established and maintained to ensure the quality of services provided for the 1 of 1 specialty (histopathology) by the laboratory from 02/11/2021 to the date of survey. Findings include: 1. The laboratory's Quality Assessment policy stated that "The Laboratory Director or designee, will review the laboratory records bi-annual for the following quality factors: Patient Test Management, Quality Control, Proficiency Testing, Maintenance, Inventory, Communications, Complaints. The quality factors will be rated satisfactory or unsatisfactory on the Quarterly Assessment form." 2. On the date of survey, 02/22/2023 at 10:53 am, the laboratory could not provide documentation for the bi-annual review performed from 02/11/2021 to 02/22/2023. 3. The laboratory performed 477 and 628 microscopic examinations for histopathology in 2021 and 2022, respectively. 4. The LD confirmed the findings above on 02/22/2023 around 11:15 am.</p>
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p>

This STANDARD is not met as evidenced by:
Based on review of competency assessment records and interview with the Laboratory Director (LD) and Office Manager (OM), the Technical Supervisor (laboratory director, CMS 209 personnel # 1) failed to evaluate and document the performance of 4 of 5 testing personnel (TP) responsible for the microscopic examinations for histopathology at least semiannually during their first year from May 2021 to the day of survey. Findings include: 1. On the date of survey, 02/22/2023 at 10:17 am, the Office Manager interviewed confirmed that TP#3, #4 and #5 joined the practice in April 2022. The TP#6 joined the practice in May 2021 and left the practice in March 2022. 2. At the time of survey, the laboratory could not provide semiannual competency assessment documentation for 4 of 5 TP (CMS 209 personnel # 3, #4, #5, #6) who performed microscopic examinations for histopathology during their first year. 3. The laboratory performed 477 and 628 microscopic examinations for histopathology in 2021 and 2022, respectively. 4. The LD and OM confirmed the findings above on 02/22/2023 around 11:15 am.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
Based on review of the laboratory competency assessment records and interview with the Laboratory Director (LD), the Technical Supervisor (laboratory director, CMS 209 personnel # 1) failed to evaluate the competency assessment for 5 of 5 Testing Personnel (TP) who performed microscopic examinations for histopathology from 02/11/2021 to the day of survey. Findings include: 1. At the time of inspection, the competency assessment documents provided by the laboratory for 5 of 5 TP (CMS 209 personnel #2, #3, #4, #5, #6) who performed microscopic examinations for histopathology from 02/11/2021 to the day of survey were signed by the individual TP (who were not listed as Technical Supervisor on the CMS 209 form) as "Evaluator". 2. The competency assessment documents provided did not show that the competency assessment was performed by the Technical Supervisor. 3. The laboratory performed 477 and 628 microscopic examinations for histopathology in 2021 and 2022, respectively. 4. The LD confirmed the findings above on 02/22/2023 around 11:15 am.